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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,235	06/11/2002	Jaak Decuypere	DCLQ:003	5573

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EXAMINER	
MARX, IRENE	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,235	DECUYPERE ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/13/05*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,8-12,14 and 20-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 8-12, 14 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 6/13/05 is acknowledged.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Claims 1-3, 8-12, 14 and 20-25 are being considered on the merits.

Claims 15-19 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 8-12, 14 and 20-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present as-filed specification for a range of " about 0.05 to about 20% triglyceride" as now recited. The original claims of the instant application do not have this range in original claim 13, for example. The original claims in the PCT document are irrelevant to the present record, since they were amended prior to the filing of the instant case under 35 U.S.C § 371.

Therefore this material is new matter and must be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 8-12, 14 and 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that "triglyceride composition" lacks internal antecedent basis. The feed composition comprises "triglyceride" In addition the amount of "ppm" for the enzyme is confusing. Generally enzymes are characterized by units of activity rather than by concentration.

Claims 9-12 fail to find proper antecedent basis in claim 1 for "said lipolytic" in claim 1 the term is "active lipolytic"..

Claims 22 and 24, respectively 23 and 25 are vague and indefinite and appear to be duplicates. The distinction between "in major part" and "substantially", if any, is unclear from the present record. In addition, no definition is provided for either term. Therefore, the meaning intended is uncertain. Is it 50.001, 50.1%, 60%, 80% etc.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant indicates that the recitation "ppm" is used in the specification to denote concentration. This may be so. However, it does not provide information about the activity of the enzyme intended.

Therefore the rejection is deemed proper and it is adhered to.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 8-11 and 20-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by breast milk from humans and other animals as evidenced by Tang *et al.* and Hurley for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to nutritional composition containing at least one triglyceride containing one or more C4-12 medium chain fatty acids and at least one active lipolytic enzyme, comprising about 0.25 to about 10 % triglyceride and about 100 to about 10.000 ppm lipolytic enzyme.

Breast milk contains about 4% triglycerides as evidenced by Hurley and naturally contains about 100 ppm (0.1 mg/ml) of active bile-salt activated lipase among the lipases in the composition.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant has misinterpreted the rejection as relying on Tang and Hurley. This is incorrect. The rejection is over breast milk of humans and other lactating animals.

The crux of the rejection is that breast milk of humans and other lactating animals is the same as the composition as claimed. Tang and Hurley were cited as evidence of the usual composition of human breast milk. Applicant has not provided evidence that breast milk from a lactating animal does not contain active digestive or lipolytic enzymes in the concentration as claimed.

In response the arguments directed to "industrial preparation", the mode of preparation of a triglyceride does not alter the intrinsic properties thereof. A medium chain triglyceride prepared "industrially" is chemically indistinguishable from a naturally produced medium chain triglyceride, and applicant has not demonstrated otherwise.

Regarding the alleged benefits of specific concentrations and ratios, they do not pertain to the invention as claimed. Regarding "high" content of certain medium chain fatty acids, the amount intended is not clearly delineated in the claims. It is also of interest to emphasize that at the claimed 0.05% concentration of triglyceride, it is doubtful that the touted benefit are accrued. Moreover, and more importantly, applicant has not demonstrated with objective evidence a patentable distinction between the composition as claimed and human or other breast milk .

Therefore the rejection is deemed proper and it is adhered to.

Claims 1-3, 8-12, 14 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hull *et al.* taken with Haas *et al.* and Tang *et al.* for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues each of the references individually. However, "[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." In re Merck & Co. Inc, 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

In this regard, applicant appears to fail to appreciate also that the rejection is an obviousness rejection and not an anticipation rejection.

The examiner is relying on the teachings of Tang to demonstrate that the combination of triglycerides with active lipolytic enzymes is old and well known in the art. In addition, in Haas in Example 1, a composition is prepared and disclosed comprising active pancreatic lipase. Thus the argument fails to persuade.

Regarding the alleged benefits of a composition disclosed in the specification to early weaned animals, the arguments do not pertain with any particularity to the invention as claimed. Moreover, the claims are directed to a composition and not to a method of treating early weaned animals.

Regarding "high" content of certain medium chain fatty acids, the amount intended is not clearly delineated in the claims. It is also of interest to emphasize that at the claimed 0.05% concentration of triglyceride, it is doubtful that the touted benefit are accrued.

With respect to the alleged criticality of concentration lipase criticized in Haas, the invention as claimed does not even require lipase, except in claims 9 and 11. The rest of the claims are directed to "lipolytic enzyme". Moreover the amount of 100 ppm as claimed does not

in any way provide criticality for concentration, particularly in the absence of an indication of the enzymatic activity. Moreover, there is no clear correlation between the claim designated composition and the extensive unexpected results touted (Response, pages 11-12). The results in the specification pertain to specific compositions having specific ingredients in specific concentrations and not to the invention as claimed.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651